

**IN THE UNITED STATES DISTRICT COURT
WESTERN DISTRICT OF VIRGINIA
ABINGDON DIVISION**

UNITED STATES OF AMERICA

v.

CASE NO. 1:19cr00016

**INDIVIOR INC. (a/k/a Reckitt Benckiser
Pharmaceuticals Inc.) and
INDIVIOR PLC**

**REPLY IN SUPPORT OF DEFENDANTS'
MOTION FOR BILL OF PARTICULARS**

As the government acknowledges in its Response in Opposition to Indivior's Motion for Bill of Particulars (hereinafter "Gov. Response"), a defendant is entitled to know the essential elements of every crime charged in an indictment. *See* Gov. Response at 5 (ECF No. 164). That is what Indivior Inc. and Indivior PLC (collectively, "Indivior") are seeking here. To be clear, Indivior is not asking the government to provide a detailed disclosure of evidence at this stage. It is simply asking that the government provide sufficient detail about the nature of the charges asserted in the Indictment so that it can effectively prepare for trial. *See United States v. Sampson*, 448 F. Supp. 2d 692, 696 (E.D. Va. 2006) (ordering the government to provide a bill of particulars to allow the defendant the opportunity to "more appropriately defend the charges" at trial).

The government has refused to provide this information in every category requested. Even where Indivior is simply requesting the identity of co-conspirators or the critical information about each purportedly false statement the government intends to prove at trial—information that courts have routinely required the government to provide—the government has refused. Moreover, it remains unclear to Indivior whether, and if so how, the government intends to charge that Indivior somehow aided and abetted physicians in prescribing or

dispensing Suboxone Film in a “careless and clinically unwarranted manner.” Indivior “should not have to waste precious pre-trial preparation time guessing” about the nature of the government’s charges when the government knows precisely the nature of the charges it is asserting and “can easily provide the information.” *United States v. Trie*, 21 F. Supp. 2d 7, 21 (D.D.C. 1998). Indivior respectfully requests an order requiring the government to address in a bill of particulars each of the omissions in the Indictment.

I. The government must disclose each of the false or fraudulent statements it intends to introduce at trial and the factual basis for the alleged falsity or fraudulence.

The government dismisses Indivior’s request for the details surrounding the false or fraudulent statements it intends to introduce at trial, apparently arguing that the information contained in the Indictment is sufficient. It is not. Bills of particulars are warranted when an indictment fails to delineate each fraudulent statement that the government seeks to introduce at trial and the basis for its alleged fraudulence. *See, e.g., United States v. Magalanik*, 160 F. Supp. 3d 909, 918 (W.D. Va. 2015) (ordering government to list “the specific visa and/or work applications that it intends to introduce at trial and explain, in general terms, how each application is believed to be false or fraudulent”); *United States v. Elbaz*, 332 F. Supp. 3d 960, 982-83 (D. Md. 2018) (ordering government to list all allegedly false statements “that it intends to introduce at trial, including the date of the statement and the person to whom it was made”); *United States v. Anderson*, 441 F. Supp. 2d 15, 20 (D.D.C. 2006) (holding that the defendant is “entitled to know precisely which allegedly false statements the government relies on in each paragraph, the way in which the government alleges them to be false, and when approximately they were allegedly made”). Here, the Indictment is lacking on both fronts.

In its Response, the government points to a “30-paragraph chart” in the Indictment identifying a set of allegedly false and fraudulent statements it attributes to Indivior. Gov.

Response at 1. But as Indivior raised in its opening brief, the Indictment suggests that the allegations in that chart are only “illustrative examples,” rather than “an exhaustive list” of all the purportedly false and fraudulent statements the government intends to introduce at trial.

Indictment ¶ 42 n.2 (ECF No. 3); *see also* Memorandum in Support of Defendants’ Motion for Bill of Particulars, at 7 (ECF No. 137). The government readily acknowledges this classification in its Response, referring to these again as just “examples” of false and fraudulent statements. Gov. Response at 7-8, and including elusive phrases like “and more” after listing a handful of sweeping statements from the Indictment that it claims will support its theory, Gov. Response at 2. In addition, the Indictment alleges a conspiracy and fraudulent conduct that lasted from 2006 through the date of the Indictment in 2019, Indictment ¶¶ 31-32, 78, but does not identify a single allegedly false or fraudulent statement or representation made after 2016.¹ Although the government seems to suggest that it has otherwise identified all the alleged statements and representations and “provided these documents to Indivior on a disc,” *see* Gov. Response at 3, Indivior is unaware of any identification of every false and fraudulent statement the government intends to introduce at trial, or any specific “disc” containing an overtly delineated subset of materials that would otherwise make this information clear.

In addition, while the government points to allegations in the Indictment showing that there was once a question as to whether Indivior’s statements about Suboxone Film may have lacked substantiation, *see* Gov. Response at 2, 8, it does not disclose its basis for charging that

¹ As Indivior noted in its opening brief, to the extent the government identifies additional false or fraudulent statements or representations in a bill of particulars that are different from those alleged in the Indictment, Indivior reserves the right to challenge the government’s ability to introduce such statements at trial. *See, e.g., United States v. Floresca*, 38 F.3d 706, 712-14 (4th Cir. 1994) (en banc) (finding plain error where the district court failed to address the government’s constructive amendment of the indictment thereby “destroy[ing] the defendant’s substantial right to be tried only on charges presented in an indictment returned by a grand jury” (quoting *Stirone v. United States*, 361 U.S. 212, 217 (1960))).

Suboxone Film was *not* safer, less susceptible to diversion, or less susceptible to pediatric exposure.² The government points to the Food and Drug Administration's ("FDA") denial of Indivior's Citizen Petition in which it asked that the agency require all manufactures of buprenorphine products to implement unit-dose, child-resistant packaging as a matter of public safety, Gov. Response at 2, but it does so without acknowledging that all four of the FDA divisions and offices that considered the issue agreed that "Suboxone film in unit-dose packaging poses a lower overall risk of accidental pediatric exposure than Suboxone tablets in multi-dose packaging"³ or that the FDA later recommended that generic buprenorphine manufactures voluntarily switch to unit-dose packaging for their buprenorphine-containing products.⁴ Perhaps these are the only bases the government intends to present at trial regarding the purported falsity of these statements, but if the government has some other basis to contend that the statements were actually false, it must provide that information to Indivior in a bill of particulars for each specific statement or representation to allow Indivior to prepare for trial and to prevent undue surprise.

² For example, in response to Indivior's request for the basis for charging these statements are false, the government responds that "Indivior had no studies showing" that the statements were true at the time. Gov. Response at 2. Putting to one side the inaccuracy of this statement, it does not answer the question asked. Whether Indivior had studies specifically supporting statements made at the time does not speak to their ultimate truth, and the purported absence of supporting studies does not make any statements fraudulent.

³ Citizen Petition Response from Food & Drug Admin. Center for Drug Evaluation and Research, Office of Surveillance and Epidemiology (Feb. 14, 2012) (RBP0114_19147715); see also Citizen Petition Response from Division of Anesthesia, Analgesia, and Addiction Products (Dec. 6, 2012) (RBP0114_19147735); Citizen Petition Response from Division of Medication Error Prevention and Analysis (Feb. 14, 2013) (RBP0114_19147756-57); Citizen Petition Response from Division of Epidemiology (Feb. 14, 2013) (RBP0114_19147802).

⁴ Buprenorphine Prod. Mfrs. Grp. (BPMG), Meeting Minutes of FDA Call on BTOD REMS Submission 3-5 (Apr. 9, 2013) (RBP0114_19147639).

II. The government must disclose the particulars of its apparent claim that Indivior aided and abetted physicians in prescribing in a “careless and clinically unwarranted manner.”

The Indictment also alleges that Indivior somehow aided and abetted physicians in prescribing and dispensing Suboxone Film in a “careless and clinically unwarranted manner.” Indictment ¶ 31.⁵ In describing the purported scheme to defraud, the government separately lists “(A) making materially false and fraudulent statements and representations to health care providers to induce them to prescribe, dispense, and recommend Suboxone Film;” and “(D) marketing Suboxone Film to health care providers to be prescribed and dispensed in a careless and clinically unwarranted manner.” *Id.* But the nature of the latter charge, and the essential elements of that charge, remain a mystery. For example, the Indictment does not define what it deems to be “careless and clinically unwarranted” prescribing or dispensing, address how Indivior’s marketing aided physicians in prescribing or dispensing Suboxone Film in a “careless and clinically unwarranted” manner, or link any false or fraudulent statements to the purported “careless and clinically unwarranted” prescribing practices.

In its Response, the government points back to the allegations in the Indictment addressing Indivior’s alleged marketing of Suboxone Film and inclusion of certain doctors in a telephone referral program, known as “Here to Help,”⁶ but it fails to provide any link between

⁵ See also Indictment at 26 (suggesting that a charged scheme includes “marketing Suboxone Film to health care providers to be prescribed and dispensed in a careless and clinically unwarranted manner”).

⁶ Included among the paragraphs the government cites in its Response are another series of “illustrative examples” of communications attributed to Indivior, but not an “exhaustive list.” *Id.* ¶ 102 n.5. To the extent the government can provide some link between these communications and the purported careless prescribing and dispensing, it must also state in a bill of particulars whether there are other actions or communications omitted from the Indictment it intends to prove at trial to support its claim.

these allegations and the doctor's purported careless prescribing practices in a way that could give rise to fraud charges.⁷ See Gov. Response at 3. Indivior thus has no basis to understand the nature of this purported claim. The government must therefore state with particularity the details it believes support its allegation that Indivior's marketing somehow *caused* certain physicians to engage in careless prescribing and dispensing.

III. The government must provide the particulars of its conspiracy charge.

In its Response, the government does not even address Indivior's request that it disclose the identity of Indivior's purported co-conspirators. Although the Indictment alleges that between 2006 and 2019, Indivior conspired with "others known and unknown to the Grand Jury" to commit mail fraud, wire fraud, and health care fraud, it does not identify a single co-conspirator. Indictment at p. 36. Courts have routinely ordered bills of particulars requiring the government to disclose the names of co-conspirators. See, e.g., *United States v. Am. Waste Fibers Co.*, 809 F.2d 1044, 1047 (4th Cir. 1987) (proper remedy for indictment that omits names of co-conspirators is to seek a bill of particulars); *United States v. Coleman*, No. 3:17-CR-00008, 2018 WL 1386265, at *5 (W.D. Va. Mar. 19, 2018) (directing the government to disclose in a bill of particulars "the names of the co-conspirators the Government may use as witnesses"); *United States v. Allen*, 289 F. Supp. 2d 230, 238 (N.D.N.Y. 2003) (directing government to disclose "the identities of all persons the government claims to have been co-conspirators during the course of the alleged conspiracy, regardless of whether they have been indicted"); *United*

⁷ With regard to the Here to Help calls, the Indictment does not indicate whether any "connect[ion]" of patients to a particular doctor even occurred. See Indictment ¶ 1. For example, the Indictment does not explain whether the doctor was simply a name among those read out by the operator within the geographic area of the caller or whether the call was ever transferred to a doctor's office. Moreover, for each of these purported calls, the Indictment does not address whether an appointment was made with a doctor, whether a patient kept that appointment, whether the relevant doctor ever saw the patient, or whether the doctor ever prescribed Indivior's product to the patient. Any "connection" between these alleged "referrals" and actual prescribing or dispensing by the doctor remains unclear.

States v. Lonzo, 793 F. Supp. 57, 60 (N.D.N.Y. 1992) (similar); *United States v. Holman*, 490 F. Supp. 755, 762 (E.D. Pa. 1980) (similar). The government fails to provide any response as to why it need not do so in this case.

Moreover, while the government contends it has provided sufficient detail in the Indictment regarding the scheme that underlies its conspiracy charge, it cannot point to any place in the Indictment addressing an actual agreement among purported co-conspirators forming the basis of a conspiracy, let alone any pertinent details regarding the scope of any such agreement. Here too, courts have routinely ordered the government to provide such information in a bill of particulars. *See Coleman*, 2018 WL 1386265, at *5 (granting the defendant's request for a bill of particulars to "summarize[e] the agreement or agreements constituting the conspiracy charge" in light of the potential that the defendant could otherwise be subject to surprise at trial or be unable to comprehend the charges against him); *United States v. Garibalde-Barron*, No. EP-12-CR-1406-KC, 2013 WL 427389, at *5 (W.D. Tex. Feb. 4, 2013) (requiring the government to specify in a bill of particulars "when the agreement took place, with whom the agreement was made, and the nature of the agreement"); *United States v. Hsia*, 24 F. Supp. 2d 14, 32-33 (D.D.C. 1998) (ordering the government to produce a bill of particulars addressing "the scope of the alleged conspiratorial agreement" and whether and how "the acts of concealment alleged in the indictment were within the scope of the conspiracy charged"). The government again fails to respond as to why it need not do so in this case. It instead points back to nearly all of the acts alleged in connection with the other twenty-seven Counts in the indictment without indicating which of those it alleges are overt acts in furtherance of the purported conspiracy. This approach fails to give Indivior any actual notice of the nature of the charged conspiracy, and significantly hampers Indivior's preparation of its defense.

IV. The government must specify all location information surrounding the alleged referrals to Doctor A.

In connection with its apparent claim that Indivior somehow aided certain physicians' purported careless prescribing practices, the Indictment alleges that Indivior used a telephone referral program, known as "Here to Help," to "connect patients to doctors Indivior knew were prescribing Suboxone and/or other opioids" in such a manner. Indictment ¶¶ 1, 102. In response to Indivior's request that the government provide the specific locations from which each alleged referral to Doctor A originated, the location of the Here to Help call centers where each referral call was answered, and the locations of the doctor's offices to which each referral was purportedly made, the government points to a spreadsheet that provides some, but not all, of the requested information about each of these calls. Gov. Response at 4 (citing M2077_78_81_0000003).

In particular, the spreadsheet does not identify the location where each of the listed Here to Help calls originated. It instead provides incomplete information regarding the address of the patients who apparently initiated the calls. This incomplete address information does not substitute for the location information associated with the actual calls that are alleged to support a number of the charges in the Indictment. *See, e.g., United States v. Jones*, No. 7:16-cf-30026, 2017 WL 1169754, at *2 (W.D. Va. Mar. 27, 2017) ("There is a long history of courts directing the government to provide a bill of particulars where the location of the alleged criminal conduct is unclear in the indictment."); *Holman*, 490 F. Supp. at 762 (ordering the government to disclose "the exact date and place, if known . . . , of each event alleged in the indictment for which such information has not yet been given"). The spreadsheet also does not include the location of the Here to Help call centers where each referral call was answered. Given that the location of these

calls is unclear in the Indictment, the government must provide this information to Indivior so that it can effectively prepare for trial.

V. The government must clarify the actions it attributes to Indivior PLC, rather than Indivior Inc.

Finally, in response to Indivior's request for the identification of any fraudulent statements or representations purportedly made or any alleged actions taken by Indivior PLC, the government points to a selection of paragraphs in the Indictment that allege actions that the Indictment attributes to Indivior Inc., arguing that the individuals mentioned in these paragraphs were actually employed by Indivior PLC. Gov. Response at 4 (citing Indictment ¶¶ 22, 26, 29, 35, 41, 74-76, 84, 87, 112, 142, 147). It thus remains unclear whether the government is attributing these actions to Indivior Inc. or now alleging that the actions are actually attributable to Indivior PLC. This leaves Indivior PLC in the same place, understanding only that the government generally asserts that Indivior PLC was involved in the alleged fraud scheme, but without any understanding of the particulars of the purported fraudulent conduct or statements the government specifically attributes to Indivior PLC. Without this information, Indivior PLC will be subject to unfair surprise at trial and unable to adequately prepare a defense.

CONCLUSION

For the foregoing reasons, and for the reasons stated in its Memorandum in Support of Defendants' Motion for Bill of Particulars, Indivior respectfully requests that the Court enter an order requiring the government to produce a bill of particulars providing separately and specifically for each of Indivior Inc. and Indivior PLC, the following information:

1. Every false or fraudulent statement or representation the government intends to introduce at trial;

2. The factual basis for the government's assertion that any such statement or representation is false or fraudulent;
3. Every action or communication supporting the claim that Indivior's marketing aided or abetted physicians in prescribing or dispensing Suboxone Film in a "careless and clinically unwarranted manner," including:
 - a. The identity of any relevant Indivior representatives;
 - b. The identity of any relevant physicians or other health care providers;
 - c. The details surrounding the alleged actions or communications that purportedly caused the relevant physicians to prescribe or dispense Suboxone Film in a "careless and clinically unwarranted manner";
 - d. The basis for concluding that the prescribing or dispensing was "careless and clinically unwarranted"; and
 - e. The link between any false or fraudulent statements to the purported "careless and clinically unwarranted" prescribing practices;
4. The identity of all co-conspirators;
5. The nature of any agreement or agreements supporting the asserted conspiracy charge, including:
 - a. When the agreement took place (approximate month and year);
 - b. Where the agreement took place (the relevant judicial district); and
 - c. The identity of the individuals or entities entering into the agreement;
6. The specific overt acts committed in furtherance of the alleged conspiracy;

7. The specific location from which each Here to Help call originated that allegedly resulted in a referral to Doctor A and the location of the Here to Help call center where each referral call was answered.
8. Any actions attributable to Indivior PLC, including:
 - a. The dates of any purported fraudulent conduct;
 - b. The identity of any specific fraudulent documents reflecting action by Indivior PLC;
 - c. Any fraudulent statements attributable to Indivior PLC; and
 - d. The factual basis for the government's assertion that any such statement or representation is false or fraudulent.

Dated: October 1, 2019

Respectfully submitted,

INDIVIOR INC. (a/k/a Reckitt Benckiser
Pharmaceuticals Inc.) and INDIVIOR PLC

/s/ Thomas J. Bondurant, Jr.

By Counsel

Thomas J. Bondurant, Jr.
Gentry Locke
10 Franklin Road SE
Roanoke, Virginia. 24022
(540) 983-9389
bondurant@gentrylocke.com

Jennifer S. DeGraw
Gentry Locke
10 Franklin Road SE
Roanoke, Virginia. 24022
(540) 983-9445
degrow@gentrylocke.com

Leigh A. Krahenbuhl (admitted *pro hac vice*)
Jones Day
77 West Wacker Drive
Chicago, Illinois 60601
(312) 269-1524
lkrahenbuhl@jonesday.com

James R. Wooley (admitted *pro hac vice*)
Jones Day
901 Lakeside Avenue
Cleveland, Ohio 44114
(216) 586-7345
jrwooley@jonesday.com

James P. Loonam (admitted *pro hac vice*)
Jones Day
250 Vesey Street
New York, New York 10281
(212) 326-3808
jloonam@jonesday.com

Peter J. Romatowski (admitted *pro hac vice*)
Jones Day
51 Louisiana Avenue NW

Washington, D.C. 20001
(202) 879-7625
pjromatowski@jonesday.com

Counsel for Defendants

CERTIFICATE OF SERVICE

I hereby certify that I caused the foregoing to be presented to the Clerk of the Court for filing and uploading to the CM/ECF system, which will send notification of such filing to all counsel of record, on this 1st day of October, 2019.

/s/ Thomas J. Bondurant, Jr.

Counsel for Defendants